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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,582	07/01/2003	Rajneesh Taneja	ABB01259P00330US (6951.US)	5225
7590 06/07/2007 TAP Pharmaceutical Products, Inc. Attention: Mark J. Buonaiuto 675 North Field Drive Lake Forest, IL 60045			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 06/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/611,582	Applicant(s) TANEJA, RAJNEESH	
	Examiner Melissa S. Mercier	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Melissa Mercier. Contact information is provided at the end of this Office Action.

Summary

Receipt of Applicants Remarks and Amended Claims filed on September 6, 2006 is acknowledged. Claims 1-8 are pending in this application. Claims 1-8 are rejected.

Applicants' arguments, filed September 6, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 7 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by WO 02/45692.

WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension to be administered to a patient in need thereof. The reference teaches adding inorganic basic salts (page 6). Among the proton pump inhibitors listed was lansoprazole (page 1, and example 6, page 13). The dosage form is in the form of a powder and prior to administration the active agent is combined with

the liquid vehicle (page 3). Example C discloses the composition is suspended in purified water. Water is a liquid vehicle with a pH of greater than 6.5. As a suspension is formed in Example C then it is the position of the examiner that the composition has a viscosity sufficient to form a suspension.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that WO '692 does not disclose or suggest Applicant's invention. The compositions of WO '692 comprise an aqueous base, an excipient, a thickener and a matrix composed of at least one paraffin (See, WO '692, page 3, first full paragraph). These compositions are very different from the compositions claimed by Applicants, which do not comprise a paraffin wax. Specifically, Example 6 of WO '692 discloses how to prepare a matrix composition. Example C discloses how to make a suspension of the matrix composition prepared according to Example 6. Since the matrix composition of Example 6 is significantly different from the compositions claimed in the instant invention (namely, the compositions of the present invention do not comprise a paraffin wax), then a suspension of Example C is also very different from instantly claimed compositions. It is noted by the examiner that applicant has used the terminology "comprising" allowing for the inclusion of any number of components regardless of their material effect on the composition.

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 102(b) as being unpatentable over WO 94/25070.

WO '070 teaches a pharmaceutical composition for oral administration to animals comprising a proton pump inhibitor in the form of beads that are enterically coated and incorporated with a pH buffer into water or a water solution (claim 6). Water is a liquid vehicle that has a pH greater than 6.5. The suitable pH buffers are used to improve the functional stability of the composition (page 8). The proton pump inhibitor is lansoprazole (claim 11). The reference also teaches making a kit comprising the dry enteric-coated beads (claims 14, 15), and the enterically coated beads are added to a liquid vehicle, such as water.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Independent claims 1, 7 and 8 recite composition or kit comprises "a liquid vehicle having a pH greater than 6.5 and a viscosity sufficient to maintain a uniform suspension of the PPI". Applicants submit that WO '070 does not disclose compositions comprising such a liquid vehicle. Rather, WO '070 discloses paste-like .gel compositions comprising proton pump inhibitors (See, WO '070, page 3). It is the examiners position that the instant claims recite a "liquid vehicle" is present, such as recited in the prior art reference. The claims do not require the composition is in liquid form as it being argued.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/45692.

WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension to be administered to a patient in need thereof. The reference teaches adding inorganic basic salts (page 6). Among the proton pump inhibitors listed was lansoprazole (page 1, and example 6, page 13). The dosage form is in the form of a powder and prior to administration the active agent is combined with the liquid vehicle (page 3). Example C discloses the composition is suspended in purified water. Water is a liquid vehicle with a pH of greater than 6.5. As a suspension is formed in Example C then it is the position of the examiner that the composition has a viscosity sufficient to form a suspension. The reference also teaches making different dosage forms with different dosage amounts of the active agent (page 10). Thus it would have been obvious to one of ordinary skill in the art to make a dosage form that comprises two doses of the proton pump inhibitor.

Although the reference does not teach the specific viscosity requirement it would be obvious to one of ordinary skill in the art to adjust the thickening ingredients in the composition to achieve the desired viscosity.

The reference does not specifically disclose a kit composition. However it does disclose first making the microgranules and then adding them to a liquid vehicle. It would have been obvious to one of ordinary skill in the art that the two components, the microgranules and the liquid vehicle would first need to be in separate containers before they are mixed. Thus a kit comprising two separate containers, one comprising the

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microgranules of acid labile active agent (proton pump inhibitor) and the other the liquid vehicle would be obvious to one of ordinary skill in the art.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/25070.

WO '070 teaches a pharmaceutical composition for oral administration to animals comprising a proton pump inhibitor in the form of beads that are enterically coated and incorporated with a pH buffer into water or a water solution (claim 6). Water is a liquid vehicle that has a pH greater than 6.5. The suitable pH buffers are used to improve the functional stability of the composition (page 8). The proton pump inhibitor is lansoprazole (claim 11). The reference also teaches making a kit comprising the dry enteric coated beads (claims 14, 15), and the enterically coated beads are added to a liquid vehicle, such as water.

The reference does not teach the viscosity requirement.

One of ordinary skill in the art would be motivated to make a solution with a viscosity that is suitable to form a suspension. One of ordinary skill in the art would know how to add thickening agents and other ingredients to achieve the desired viscosity.

Response to Arguments

Applicant has not submitted any additional arguments regarding the above Claim Rejections under 35 USC § 103 rejections that have not been address above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

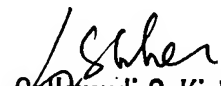
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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